

DATE OUT: 23/AUG/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D275892 REG./File Symbol No.: 73766-R
PRODUCT NAME: Gourmet Ant Bait Gel

FROM: Shyam Mathur, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

S Mathur
8-23-01

TO: Arnold Layne, PM 03
Insecticide Branch/RD(7505C)

INTRODUCTION:

The registrant has submitted product chemistry data to support the registration of the subject end-use product. The product chemistry data were submitted under MRID No. 454345-01. The Subgroup B data (Physical/Chemical Properties) were submitted under Self Certification program in compliance with PR Notice 98-1.

SUMMARY OF FINDINGS

1. The subject product contains [REDACTED] as the active ingredient with product label claim of 6.0%.

2. The CSF for the basic formulation(dated 12-27-00)is not filled out correctly and completely. It is not in compliance with PR Notice 91-2. The nominal concentration of AI(5.88%) does not agree with the label claim nominal concentration (6.0%). The data submitted corresponding to the guideline reference 830.1550(Product Identity)and 830.1750(Certified limits)do not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

3. The proposed lower certified limits for most of the inert ingredients are below the standard lower certified limits and the proposed upper certified limits are above the standard certified limits. For more details please refer to Confidential Appendix.

4. The data submitted corresponding to the guideline reference 830.1650(Description of formulation process)and 830.1670(Discussion on the formation of impurities) satisfy the data requirements of 40CFR158.165 and 158.167 respectively.

Product ingredient source information may be entitled to confidential treatment

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5. The data submitted corresponding to the guideline reference 830.1800 (Enforcement of analytical method) satisfy the data requirements of 40CFR§158.180.

6. The data submitted corresponding to guideline reference color (830.6302), odor (830.6304), Physical state (830.6303), density (830.7300), pH (830.7000), Oxidation/Reduction (830.6314), Flammability (830.6315), Explodability (830.6316), Viscosity (830.7100), Miscibility (830.6319), and Dielectric breakdown voltage (830.6321) satisfy the data requirements of 40CFR§158.190. These data were submitted under self certification program.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the subject end-use product and has concluded that:

1. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup A and Subgroup B (Physical/Chemical properties) satisfy the data requirements of 40CFR§158.150 to 158.190 and are acceptable, except for the CSF for the basic formulation.

2. The CSF for basic formulation (dated 12-27-00) is not acceptable for the following reasons:

i. The proposed lower certified limits for all of the inert ingredients are below the standard lower certified limits as per table in 40CFR§158.175.b.2. The proposed upper certified limits are above the standard upper certified limits. The registrant must provide proper justifications for the proposed certified limits.

ii. The nominal concentration of the active source product with Reg. No. [REDACTED] The registrant must use the purity of 98% to calculate the nominal concentration of the AI in the formulated product. The proposed upper and lower certified limits for the AI must be calculated based on the nominal concentration (5.88%).

The registrant must submit the revised CSF taking into consideration all the points indicated in the item #2.

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 DATE: 08-23-01

1. Reviewer: S.B.Mathur 2. Company: Innovative Pest Control Products
3. Type of Submission: Registration [X] Reregistration []
 New [X] Resubmission [X] Amendment [] "ME-TOO" []
 Alternate Formulation [] Experimental Use Permit []
 Other (Specify) _____
4. If "Me-TOO" Registration, this product is [] is not []
 similar or substantially similar to EPA's Reg. No.: _____

If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 • Non-integrated formulation system.....[X]
 • Are all technical grade active ingredients used registered?
 • yes [Y] • no [], If no, specify _____
 • Integrated formulation system.....[]
6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
- 6(a) Formulation intended for food use under 40CFR§180.1001:
 • yes [] • no [X] • Some are cleared, others are not []
 Cleared under list: • c [] • d [] • e []
 Are there any limitations for use as an inert under 40CFR§180.1001?
 • yes [] • no [], If yes, specify _____
- 6(b) Formulation intended for non-food use:
 • yes [X] • no [] • Some are cleared, others are not []
- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).
 • yes [] • no [] • Some are cleared, others are not []
 If yes, the entire formulation is cleared under 21CFR§_____

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 830.7300 (density), 830.7000 (pH), and 830.6315 (Flammability), respectively:
• yes [X] • no []
8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
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9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
• yes [] • no [X]
10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:
• yes [] • no [X]

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes [X] • no []
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
• yes [] • no [] • not applicable [X]
13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
• yes [X] • no []

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

<u>14. Chemical IDs/Manufacture/ Analytical Information</u> New Guideline:830.--	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
1550. Chemical Identity(CSF)	U	12-27-00
1600. Beginning Materials	Y	454345-01
1650. Formulation Process	Y	
1670. Discussion of Impurities	Y	" "
1700. Preliminary Analysis	NA	
1750. Certified Limits(CSF)	U	12-27-00
1800. Enforcmnt. of Anal.Method	Y	454345-01

<u>15. Physical/Chemical Properties</u> New Guideline No. 830.---	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
6303. Physical State	Y	Gelatin	454345-01
7300. Density/Bulk Den.	Y	11.55 lbs/g	" "
7000. pH	Y	4.0	" "
6314. Oxid/Red Action	Y	none	" "
6315. Flamm.-Flsh Pt.	Y	No flash Pt. seen at 60° C	" "
6315. Flame Exten.	NA		" "
6316. Explodability	Y	Not explosive	" "
6317. Storage Stabltly.	PR 92-5	stable for 1 year in HDPE	432167-03
7100. Viscosity	Y	1200 cps	454345-01
6319. Miscibility	Y	Immis. in pet.solvents	" "
6320. Corrosion Charac	Y	Non- corrosive	432167-03
6321. Dielec.Bkd.Vltg	NA		

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable;
G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

CONFIDENTIAL APPENDIX

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1. The proposed lower certified limits for the AI and all the inert ingredients used in the CSF for basic formulation (dated 12-27-00) are below the standard lower certified as per table in 40CFR§ 158.175.b.2. The proposed upper certified limits are higher than the standard certified limits. The registrant must provide proper justification for proposing these limits.